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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,185	06/08/2000	Ronald M. Cook	19079-000310US	2668

7590

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EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

16

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/591,185

Applicant(s)

COOK, RONALD M.

Examiner

Janet L Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment to the claims filed on 9-26-02 does not comply with the requirements of 37 CFR 1.121(c) because the marked up claim 32 does not match the clean copy of amended claim 32 entered in the record. In particular the term "group" is not present in line 2 of the clean copy of claim 32. Amendments to the claims filed after March 1, 2001 must comply with 37 CFR 1.121(c). Additionally, claim 34 in the clean copy of the claims pending after amendment is different from originally filed claim 34. The claim 34 in the currently filed response comprises an amendment to claim 34, however there is no instruction to amend claim 34.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-27-02 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 32-62 remain rejected under 35 U.S.C. 103(a) as being unpatentable for the reasons of record set forth in the Official Action mailed 5-30-01, in the rejection of claims 1-3,

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6-11, 13-26, and 28-30 under 35 USC 103(a) over Meade et al. in view of Manoharan et al. and Gold et al. for the reasons of record set forth in the official action mailed 2-7-2002.

Applicant's arguments filed 9-26-02 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the combination of cited references do not teach wherein "the non-nucleic acid stabilizing moieties (e.g., cholesterol) interact with each other to bring the energy donor and the energy acceptor into operative proximity, thereby enabling transfer of energy from the donor to acceptor." Additionally, Applicants argue that an obviousness rejection cannot be based upon an inherency argument. However, contrary to Applicant's assertions, the combined references teach or render obvious the claimed compounds, in particular the Meade et al. reference clearly provides sufficient guidance for the successful design of nucleic acid molecules comprising electron donor and electron acceptor moieties covalently bound to the ribose-phosphate backbone of said nucleic acid (Meade et al., col. 5, lines 45-53). Furthermore, Meade et al. teach the detection of electron transfer between electron acceptor/donor pairs covalently linked to a nucleic acid molecule after photoinduction, as an indication of a successful amplification (col. 12, lines 25-40). The instant rejection is based upon the combined teachings of the art which clearly support the addition of electron acceptor/donor pairs to a nucleic acid molecule, and to further modify the structure with cholesterol moieties for the purpose enhancing the cellular uptake of the structure. Applicants are claiming a structure based upon an intrinsic characteristic of the structure. The examiner has merely provided an alternative motivation to combine the teachings of the cited references to produce the compounds recited in the instant claims. The entire rejection is not dependent upon an "inherency" argument. In the instant case, the prior art clearly suggests, and provides

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sufficient motivation for the covalent attachment of Cholesterol moieties into two non-terminal positions of a nucleic acid molecule via an organic linker (see Manoharan et al.), and further provides motivation for the addition of an electron donor and an electron acceptor moiety attached to either the 5' or 3' terminus of an oligonucleotide. Applicants have not clearly set forth sufficient argument as to why the modified compounds resultant from the combination of Meade et al. in view of Manoharan et al. and Gold et al., would not possess the same properties as those compounds recited in the of the instant claims. Absent evidence of unexpected results, the compounds of Meade et al. in view of Manoharan et al. and Gold et al. have similar properties, and it is deemed that since such is the case, other claimed limitations not disclosed are inherent. Sufficient evidence of similarity is present to shift the burden to Applicant to provide evidence that the claimed products are unobviously different than the modified oligonucleotides disclosed in the references described above. Applicant's arguments to not take the place of the evidence required to render unobvious the claimed products.

As stated in the prior rejection "the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

5. Claims 32-61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al. (US 5,866,336) in view of Templeton et al. (Nature Biotechnology, 1997, Vol. 15, pages 647-652), for the reasons of record in the Official Action mailed 2-07-02.

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Applicant's arguments filed 9-26-02 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by reiterating the same arguments set forth above. See the above response to Applicant's arguments.

Conclusion

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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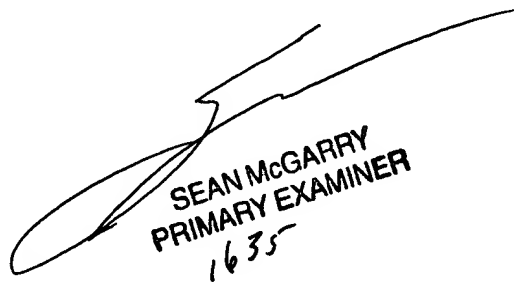
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
January 27, 2003


SEAN McGARRY
PRIMARY EXAMINER
1635